Amendment to the Drawings

The attached eight sheets of drawings includes changes to Figs. 1A-7. These sheets, which includes Figs. 1A-7, replace the original sheets including Figs. 1A-7.

REMARKS

Applicant appreciates the Examiner's thorough examination of the subject application and request reconsideration of the subject application based on the foregoing amendments and the following remarks.

Applicant also acknowledges with thanks the personal interview with Examiners Scott and Sweet concerning the above-identified Office Action, the cited art and the claims, including amedning some of the claims to distinguish from the cited art. During the interview, Applicant also was advised of an inconsistency between a drawing figure and the specification. While this concern was not included or identified in the above-identified Office Action, Applicant was asked if they could attend to the inconsistency to advance prosecution.

Claims 1, 9, 15, 26-31, 37-41, 46-49, 57-60, 65-68 and 73 are pending in the subject application. Claims 2-8, 10-14, 16-25, 32-36, 42-45, 50-56, 61-64 and 69-72 were previously canceled.

Claims 1, 9, 15, 26-31, 37-41, 46-49, 57-60, 65-68 and 73 stand rejected under 35 U.S.C. §102. Claims 31 was objected to because of an identified informality.

Claims 1, 15 and 26 were amended in the foregoing amendment so as to provide that the deflection mechanism extends within the elongated member (claims 1 & 15) or within the catheter device (claim 26). Claims 1, 15 and 26 as well as claims 27-31, 37-41, 46-49, 57-60, 65-68 and 73 were amended so that they are in better form.

Claim 30 also was amended so as to now depend from claim 27 and so as to also include the limitation of rotating the deflectable distal portion about the guide member.

Claim 31 also was amended to address the identified informality.

Claim 40 also was amended so as to now depend from claim 37 and so as to also include the limitation of rotating the deflectable distal portion about the guide member.

Claims 74-80 were added so as to further claim aspects/embodiments of the present invention.

As the amendments to the claims are supported by the originally filed disclosure (including the originally filed claims of the PCT application), entry of such amendments is respectfully requested.

The drawing figures were objected to and correction required. As also indicated above, the Examiner had noticed an inconsistency between specification and drawing figures. This inconsistency was brought to attention of Applicant during the interview and the Examiner requested correction of same (even though the concern is not specifically identified in the Office Action). Enclosed herewith are amended drawing figures that address the drawing objections. The specification also is amended in the foregoing amendment to address the inconsistency identified by the Examiner.

The amendments to the specification and drawing figures do not introduce new matter because they either are editorial in nature or are supported by the originally filed disclosure. Thus, entry of such amendments into the subject applications is respectfully requested.

35 U.S.C. §102 REJECTIONS

The Examiner rejected claims 1, 9, 15, 26-31, 37-41, 46-49, 57-60, 65-68 and 73 under 35 U.S.C. §102(b) as being anticipated by Lesh [USP 5,971,9873]. Applicant respectfully traverses as discussed below.

Because claims were amended in the instant amendment, the following discussion refers to the language of the amended claims. However, only those amended features specifically relied upon to distinguish the claimed invention from the cited prior art shall be considered as being made to overcome the cited reference. The following addresses the within rejection as to the below identified groupings of claims.

CLAIMS 1 & 9

In claim 1, Applicant claims a catheter device that includes an elongated body member having a distal portion and a deflection mechanism that is operably coupled to the distal portion

so as to cause the distal portion to deflect with respect to a longitudinal axis of the elongated body member. As indicated herein, without agreeing with the rejection and in the interests of advancing prosecution, claim 1 was amended to further provide that the deflection mechanism extends within the elongated body and is operably coupled to the distal portion.

Such a catheter device further includes a guide member and a guiding mechanism. Such a guiding mechanism is coupled to the elongated body member and configured so as to guide the guide member. Also, the guiding mechanism includes an exit portion from which the guide member exits when the guide member is being deployed from the guiding mechanism. The exit portion is disposed with respect to the distal portion so the distal portion deflects from and with respect to the guide member, when the guide member is in a deployed condition.

In contrast to the present invention, the catheter device described in Lesh does not include (a) a guiding mechanism that includes an exit portion from which the guide member exits when the guide member is being deployed from the guiding mechanism and (b) a deflection mechanism (as that term is described and used in the subject application) that is operably coupled to the distal portion so as to cause the distal portion to deflect with respect to a longitudinal axis of the elongated body member and so the distal portion also deflects from and with respect to the guide member, when the guide member is in the deployed condition. In addition, as to amended claim 1, Lesh does not describe a deflection mechanism that extends within the elongated body and is operably coupled to the distal portion.

The catheter device in Lesh includes two guide wires so that a portion of the catheter device including an ablation mechanism, can be pinned or located between two points (fixed points) and so that said portion can abut and be in contact with tissue. In this way, when the ablation mechanism is activated, a linear or line of ablated tissue is formed using such a catheter device. In contrast, the distal portion of the catheter device of the present invention is deflectable with respect to the long axis of the elongated body member as well as the from and with respect to the guide (when it is deployed). As a result of this deflectability, the deflectable portion can be

deflected and manipulated so a non-linear band of ablated tissue (e.g., a ring of ablated tissue) is formed about the guide wire.

In Lesh there also is no guiding mechanism that includes an exit portion from which the guide member exits when the guide member is being deployed from the guiding mechanism. As described in Lesh, the guide wires 3,4 are deployed and secured to tissue in the left and right pulmonary veins. After such placement of the guide wires, the catheter device (portions thereof) are advanced over the guide wires until they are disposed in the desired arrangement. For example, the distal guide tracking member 30 or distal end portion is advanced over one guidewire 3, until the first distal guidewire port 32 confronts stop 13. The other port identified by reference numeral 34 is an entrance port where the guide wire enters into the catheter until it exits at the first distal guidewire port.

The advancement of the catheter device is continued until the catheter becomes pinned between the two points defined by the two guide wires 3,4 (as described above) and until the intermediate portion of the catheter is put into contact with the tissues. In other words, such advancement in combination with the passive bending properties of the catheter allows the intermediate portion of the catheter to bend until it comes in contact with the tissues.

As to the deflection device, as indicated by Federal Circuit, in deciding the issue of anticipation, the trier of fact must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify *corresponding elements* disclosed in the allegedly anticipating reference (emphasis added, citations in support omitted). *Lindemann Maschinenfabrik GMBM v. American Hoist and Derrick Company et al.*, 730 F. 2d 1452, 221 USPQ 481,485 (Fed. Cir. 1984).

The subject specification provides that a deflection mechanism "can deflect the distal portion of the elongated body member with respect to the guide member and thus place the operable end of the distal portion in contact with the tissues to be ablated."

The subject application also provides that as known to those skilled in that art, "a catheter having a deflection mechanism is configured so that the distal portion of the elongated body

member will deflect or move (*e.g.*, curve) with respect to a longitudinal axis of the elongated body member and about a specific point from the end of the distal portion. For example, groups of wires are attached or secured to the distal portion and are arranged so that when they are operated in specific ways, the distal portion of the catheter is moved with respect to the long axis of the body member. As is also known to those skilled in the art, such deflection mechanisms can be arranged and operated so that the end of the distal portion can be deflected or curved back upon itself so the end is pointing in a direction that is opposite to the general direction of other portions of the elongated body member (*e.g.*, forming a hook like arrangement)."

In addition, the subject application provides that, "a catheter device such as that of the present invention can be configured and arranged with any one of a number of devices or mechanisms, herein referred to as a deflection mechanism, that can be actuated or operated so as to cause a distal portion 112 of the elongated body member 110 to deflect or be moved with respect to the longitudinal axis 102 of the elongated body member. For example, groups of wires are attached or secured to the distal portion and are arranged so that when they are operated in specific ways, the distal portion of the catheter is moved with respect to the long axis of the body member. In a particularly illustrative example and as illustrated in Fig. 2B, the deflection mechanism causes the distal portion 112 to be deflected with respect to a deflection point 104.

Further, the subject application provides that reference "shall be made to USP 4,960,134; 4,911,148; 5,254,088; 5,318,525; 5,441,483; and 5,456,664, as to further details and discussions of various types and forms of exemplary deflection mechanisms and/ or catheters having such deflection mechanisms, which deflection mechanisms are adaptable by one skilled in the art for use with the catheter device 100 of the present invention. Reference also shall be made to USP 4,960,134; 4,911,148; 5,254,088; 5,318,525; 5,441,483; and 5,456,664, as to further details and discussions of various types and forms of exemplary the handles or actuation mechanisms/ devices that are operably coupled to the deflection mechanisms. In this regard the teachings of the above identified patents/ publication are incorporated herein by reference. "

It is respectfully submitted that there is no mechanism, device or structure described in Lesh that corresponds in any fashion to a "deflection mechanism" as that term is used in the claims and described in the subject application.

As indicated herein, without agreeing with the rejection claim 1 was amended so as to provide that the deflection mechanism extends within the elongated body member. It is clear that the structure in Lesh leading to the bending of the catheter when the catheter is being advanced over the guide wires is not "within" the elongated body member. As shown in Fig. 3 of Lesh, such bending causing structure is external to the catheter.

Applicant also would note that as described and shown in Lesh, the first distal guidewire port 32 is located in the distal end 32 of the catheter device or the distal end portion thereof. In such a configuration, the guide wire exits from the distal end 32 of the catheter device. Such a configuration precludes the distal end portion of the catheter in Lesh from being deflected from and with respect to the guide wire when the guide wire is deployed because the guide wire is inside the distal end portion.

Applicant thus submits that Lesh does not teach, suggest such features of claim 1 or modifying the catheter device described in Lesh so as to yield the catheter device as set forth in claim 1. In addition, Lesh does not teach or describe that such a modification would be reasonably successful. In this regards, Applicant also would note that any modification to the device in Lesh so as to yield the claimed device would necessarily involve the impermissible destruction of the Lesh device.

As provided by the Federal circuit, a 35 U.S.C. §103 rejection based upon a modification of a reference that destroys the intent, purpose or function of the invention disclosed in a reference, is not proper and the prima facie case of obviousness cannot be properly made. In short there would be no technological motivation for engaging in the modification or change. To the contrary, there would be a disincentive. *In re Gordon*, 733 F. 2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Thus, claim 1 is considered to be patentable over Lesh for the foregoing reasons.

As to claim 9, this claims depends (directly or ultimately) from claim 1. Thus, claim 9 is considered to be allowable at least because of its dependency from an allowable base claim. This shall not be considered an admission that this claim is not otherwise patentable over Lesh. In this regard, Applicant makes the following further observations.

Claim 9 includes the further limitation that the guiding mechanism includes an artifact on the external surface of the elongated body member and extending axially along the elongated body member, where the artifact and the guide member are configured and arranged so the guide member is moveably retained by the artifact and so as to allow for deployment of the guide member. There is no guiding structure shown in Lesh in which the guiding mechanism is on an external surface of the elongated body member and which guiding mechansim also extends axially along the elongated body member.

It is respectfully submitted that claims 1 and 9 are patentable over the cited reference for the foregoing reasons.

CLAIM 15

Applicant respectfully submits that the above remarks distinguishing the catheter device of claim 1 from Lesh also at least applies to distinguish the catheter device of claim 15 from Lesh. This shall not be considered an admission that claim 15 is not otherwise patentable over Lesh.

It is respectfully submitted that claim 15 is patentable over the cited reference for the foregoing reasons.

CLAIMS 26-31

Applicant respectfully submits that the above remarks distinguishing the catheter device of claim 1 from Lesh also at least applies to distinguish the method for ablating tissue in particular atrial tissue of claim 26 from Lesh. This shall not be considered an admission that claim 26 is not otherwise patentable over Lesh.

As to claims 27-31, each of these claims depends (directly or ultimately) from claim 26. Thus, each of claims 27-31 is considered to be allowable at least because of their dependency from an allowable base claim. This shall not be considered an admission that these claims are not otherwise patentable over Lesh. In this regard, Applicant makes the following further observations.

Each of claims 28-31 includes the limitation(s) that the deflectable portion is being rotated about the guide wire. As indicated above in the discussion regarding claim 1, in Lesh the first distal guidewire port 32 is located in the distal end 32 of the catheter device or the distal end portion thereof. In such a configuration, the guide wire 3 extends within the distal end portion until it exits from the distal end 32 of the catheter device Such a configuration necessarily precludes the distal end portion of the catheter in Lesh from being deflected from and with respect to the guide wire when the guide wire is deployed.

It is respectfully submitted that claims 26-31 are patentable over the cited reference for the foregoing reasons.

CLAIMS 37-41 & 73

Applicant respectfully submits that the above remarks distinguishing the catheter device of claim 1 and the method of claims 26-31 from Lesh also at least applies to distinguish the method for ablating tissue in particular atrial tissue of claim 37 from Lesh. This shall not be considered an admission that claim 37 is not otherwise patentable over Lesh. In this regard, Applicant makes the following further observations.

The method of claim 37 includes, inter alia, localizing an end of the deflectable distal portion with respect to an opening in a chamber, vessel or vein of a mammalian body and deploying the guide member from the guiding mechanism so at least a distal portion thereof is deployed through the opening in, and is disposed in, the chamber, vessel or vein of the mammalian body. As described above in the discussion regarding claim 1, in Lesh the guide wires 3,4 are deployed and then the catheter device is advanced over the guide wires into the

desired arrangment. Thus, Lesh cannot describe or teach the above-described limitation of localizing the distal end and then deploying the guide member.

As to claims 38- 41 and 73, each of these claims depends (directly or ultimately) from claim 37. Thus, each of claims 38-41 and 73 is considered to be allowable at least because of their dependency from an allowable base claim. This shall not be considered an admission that these claims are not otherwise patentable over Lesh. In this regard, Applicant makes the following further observations.

Each of claims 38-41 further includes the limitation that the deflectable portion is being rotated about the guide wire. As indicated above in the discussion regarding claim 1, in Lesh the first distal guidewire port 32 is located in the distal end 32 of the catheter device or the distal end portion thereof. In such a configuration, the guide wire 3 extends within the distal end portion until it exits from the distal end 32 of the catheter device Such a configuration necessarily precludes the distal end portion of the catheter in Lesh from being deflected from and with respect to the guide wire when the guide wire is deployed.

It is respectfully submitted that claims 37-41 and 73 are patentable over the cited reference for the foregoing reasons.

CLAIMS 46-49

Applicant respectfully submits that the above remarks distinguishing the catheter device of claim 1 and the method of claims 26-31 from Lesh also at least applies to distinguish the method for treating arrhythmias of claim 46 from Lesh. This shall not be considered an admission that claim 46 is not otherwise patentable over Lesh.

As to claims 47-49, each of these claims depends (directly or ultimately) from claim 46. Thus, each of claims 47-49 is considered to be allowable at least because of their dependency from an allowable base claim. This shall not be considered an admission that these claims are not otherwise patentable over Lesh. In this regard, Applicant makes the following further observations.

Each of claims 48 and 49 includes the limitation(s) that the deflectable portion is being rotated about the guide wire. As indicated above in the discussion of claim 1 and claims 38-41, in Lesh the first distal guidewire port 32 is located in the distal end 32 of the catheter device or the distal end portion thereof. In such a configuration, the guide wire 3 extends within the distal end portion until it exits from the distal end 32 of the catheter device Such a configuration necessarily precludes the distal end portion of the catheter in Lesh from being deflected from and with respect to the guide wire when the guide wire is deployed.

It is respectfully submitted that claims 46-49 are patentable over the cited reference for the foregoing reasons.

CLAIMS 57-60

Applicant respectfully submits that the above remarks distinguishing the catheter device of claim 1, the method of claims 26-31 and the method of claim 37 from Lesh also at least applies to distinguish the method for treating arrhythmias of claim 57 from Lesh. This shall not be considered an admission that claim 57 is not otherwise patentable over Lesh. In this regard, Applicant makes the following further observations.

The method of claim 57 includes, inter alia, localizing an end of the deflectable distal portion within the left atrium of a mammalian body and with respect to an opening in a vein and deploying the guide member from the guiding mechanism so at least a distal portion thereof is deployed through the opening in, and is disposed in, the vein. As described above in the discussion regarding claim 1 and claim 37, in Lesh the guide wires 3,4 are deployed and then the catheter device is advanced over the guide wires into the desired arrangment. Thus, Lesh cannot describe or teach the above-described limitation of localizing the distal end and then deploying the guide member.

As to claims 58-60, each of these claims depends (directly or ultimately) from claim 57. Thus, each of claims 58-60 is considered to be allowable at least because of their dependency from an allowable base claim. This shall not be considered an admission that these claims are

not otherwise patentable over Lesh. In this regard, Applicant notes makes the following further observations.

Each of claims 58-60 further includes the limitation that the deflectable portion is being rotated about the guide wire. As indicated above in the discussion for claim 1 and claims 28-31, in Lesh the first distal guidewire port 32 is located in the distal end 32 of the catheter device or the distal end portion thereof. In such a configuration, the guide wire 3 extends within the distal end portion until it exits from the distal end 32 of the catheter device Such a configuration necessarily precludes the distal end portion of the catheter in Lesh from being deflected from and with respect to the guide wire when the guide wire is deployed.

It is respectfully submitted that claims 57-60 are patentable over the cited reference for the foregoing reasons.

CLAIMS 65-68

Applicant respectfully submits that the above remarks distinguishing the catheter device of claim 1, the method of claims 26-31 and the method of claim 37 from Lesh also at least applies to distinguish the method for treating left atrial arrhythmia in a left atrium of a mammalian body of claim 65 from Lesh. This shall not be considered an admission that claim 65 is not otherwise patentable over Lesh. In this regard, Applicant makes the following further observations.

The method of claim 65 includes, inter alia, positioning an end of the deflectable distal portion with respect to an a pulmonary vein extending from the left atrium and deploying the guide member from the guiding mechanism so at least a distal portion thereof is deployed through the opening in, and is disposed in, the pulmonary vein. As described above in the discussion regarding claim 1, in Lesh the guide wires 3,4 are deployed and then the catheter device is advanced over the guide wires into the desired arrangment. Thus, Lesh cannot describe or teach the above-described limitations of positioning and deploying of claim 65.

As to claims 66-68, each of these claims depends (directly or ultimately) from claim 65. Thus, each of claims 66-68 is considered to be allowable at least because of their dependency from an allowable base claim. This shall not be considered an admission that these claims are not otherwise patentable over Lesh. In this regard, Applicant notes makes the following further observations.

Each of claims 66-68 further includes the limitation that the deflectable portion is being rotated about the guide wire. As indicated above in the discussion for claim 1 and claims 28-31, in Lesh the first distal guidewire port 32 is located in the distal end 32 of the catheter device or the distal end portion thereof. In such a configuration, the guide wire 3 extends within the distal end portion until it exits from the distal end 32 of the catheter device Such a configuration necessarily precludes the distal end portion of the catheter in Lesh from being deflected from and with respect to the guide wire when the guide wire is deployed.

It is respectfully submitted that claims 65-68 are patentable over the cited reference for the foregoing reasons.

The following remarks also shall apply to each of the foregoing remarks.

As the Federal Circuit has indicated, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Or stated another way, "The identical invention must be shown in as complete detail as is contained in the ... claims. *Richardson v Suziki Motor Co.*, 868 F.2d 1226, 9 USPQ 2d. 1913, 1920 (Fed. Cir. 1989). Although identify of terminology is not required, the elements must be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990). It is clear from the foregoing remarks that the above identified claims are not anticipated by Lesh.

It is respectfully submitted that for the foregoing reasons, claims 1, 9, 15, 26-31, 37-41, 46-49, 57-60, 65-68 and 73 are patentable over the cited reference and thus, satisfy the requirements of 35 U.S.C. §102(b). Therefore, these claims are allowable.

CLAIM OBJECTIONS

As indicated above, claim 31 was objected to because of the identified formalities provided on page 3 of the above -referenced Office Action. Applicant respectfully traverses.

As provided above, claim 31 was amended to address the non-art concerns specifically identified by the Examiner. Applicant thus believes that the areas of objection have been identified and addressed in the foregoing amendment.

Accordingly, it is respectfully submitted that claim 31 is acceptable.

SPECIFICATION/DRAWING INCONSISTENCY

As indicated above, during the personal interview , the Examiner identified an inconsistency between a drawing figure and the specification. Specifically, the Examiner indicated that reference numeral 115 appearing in the drawing figures does not appear in the specification. The Examiner also had indicated (correctly) that reference numeral 215 appears to be related to reference numeral 115.

The discussion on page 18 of the subject application was amended so as to include a reference to reference numeral 115. This discussion also was amended to also make reference to reference numerals for related features appearing in two figures of the subject application. In addition, a typo is being corrected.

It is respectfully submitted that for the foregoing reasons, the specification resolves the inconsistency, satisfies applicable Patent laws and rules and is supported by the originally filed disclosure including drawing figures. Therefore, the specification is acceptable.

DRAWING OBJECTIONS

The Examiner objected to the drawing figures for the reasons provided on page 2 of the above-referenced Office Action. Attached herewith are replacement sheets including Figs. 1A-7 in which the drawing figures were corrected to address the Examiner's objections. As such the as-amended drawing figures are considered acceptable.

It is respectfully submitted that the subject application is in a condition for allowance. Early and favorable action is requested.

Applicant believes that additional fees are not required for consideration of the within Response. However, if for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, the Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105, under Order No. 62270 (71699).

Respectfully submitted,
Edwards Angell Palmer & Dodge, LLP

/ William J. Daley, Jr. /

Date: February 17, 2011 By: _____

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